

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

PENNFIELD OIL COMPANY d/b/a
PENNFIELD ANIMAL HEALTH, a
Nebraska corporation,
Plaintiff,

v.

ALPHARMA Inc., a Delaware corporation,
Defendant.

ALPHARMA Inc., a Delaware corporation,
Counterclaim-Plaintiff,

v.

PENNFIELD OIL COMPANY d/b/a
PENNFIELD ANIMAL HEALTH, a
Nebraska corporation,
Counterclaim-Defendant.

Case No. 8:09-cv-00345-LES-TDT

ANSWER AND COUNTERCLAIMS

JURY TRIAL DEMANDED

for all claims, requests for relief and issues in this action that are so triable

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Defendant and Counterclaim-Plaintiff Alpharma Inc. (“Defendant” or “Alpharma”) files its Answer and Counterclaims (“Answer”) to the Complaint of Plaintiff and Counterclaim-Defendant Pennfield Oil Company, d/b/a Pennfield Animal Health, (“Plaintiff” or “Pennfield”) as follows:

ALPHARMA’S ANSWER

1. Alpharma denies having knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 1 of the Complaint.

2. Alpharma admits the allegations of Paragraph 2 of the Complaint except that Alpharma denies that Aureomycin[®] refers to a single product.

3. Alpharma admits, with respect to allegations of Paragraph 3 of the Complaint, that based on the allegations in the Complaint, the Court has subject matter jurisdiction at this time under the statutory provisions 15 U.S.C. § 1121(a) as well as 28 U.S.C. §§ 1331, 1338(a) and otherwise denies knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 3 of the Complaint in so far as it concerns the Court’s subject matter jurisdiction. With respect to allegations of Paragraph 3 of the Complaint, Alpharma further admits that this Court has personal jurisdiction over Alpharma in this action and that venue is proper in this District. Alpharma reserves the right to defer to the Food and Drug Administration (“FDA”), the Federal Trade Commission (“FTC”), or other specialized regulatory agencies for the determination of certain issues raised in this action before the Court that fall within the primary jurisdiction of those agencies.

4. Alpharma denies the allegations of Paragraph 4 of the Complaint.

ALPHARMA’S ANSWER AND COUNTERCLAIMS

5. Alpharma denies the allegations of Paragraph 5 of the Complaint and refers the Court to the Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 301 et seq., including § 321(v) (definition of “new animal drug,” which describes certain drug products that are outside the scope of that statutory term of art) and § 360b (establishing marketing authorization standards and procedures for products that are in fact deemed “new animal drugs”).

6. Alpharma denies having knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 6 of the Complaint except that Alpharma admits that Pennfield Oil Company is the sponsor of approved New Animal Drug Applications (“NADA”) No. 138-935, which FDA’s Green Book describes as covering the following Type A Medicated Articles: Chlortetracycline-100; Chlortetracycline-100MR; Chlortetracycline-50; Chlortetracycline-60; Chlortetracycline-70; Chlortetracycline-80; Pennchlor™ 50; Pennchlor™ 50-G; Pennchlor™ 70; Pennchlor™ 80; Pennchlor™ 90; and Pennchlor™ 100MR.

7. Alpharma admits with respect to the allegations of Paragraph 7 of the Complaint that it owns NADA No. 048-761 and manufactures and sells a chlortetracycline Type A Medicated Article branded with the registered trademark Aureomycin® as approved by the FDA. Otherwise, Alpharma denies having knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 7 of the Complaint.

8. Alpharma denies having knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 8 of the Complaint except that Alpharma denies the allegations that “since Pennchlor’s® entry into the granular premix market, Alpharma has targeted advertising at Pennchlor®, touting Aureomycin® to the purchasing public as a superior, more effective granular premix than Pennchlor®.”

ALPHARMA’S ANSWER AND COUNTERCLAIMS

9. Alpharma denies the allegations of Paragraph 9 of the Complaint except that Alpharma admits the publications attached as Exhibits A through D to the Complaint were issued in approximately 2006.

10. Alpharma denies the allegations of Paragraph 10 of the Complaint except that Alpharma admits Alpharma has circulated the publication attached as Exhibit B to the Complaint to Alpharma's customers since 2006; Alpharma refers the Court to the publication attached as Exhibit B to the Complaint. Alpharma refers the court to the Food and Drug Administration to interpret the historical approval of NADA 138-935, its reliance on findings of the National Academy of Sciences/National Research Council (NAS/NRC), Drug Efficacy Study Group concerning Type A Medicated Articles containing chlortetracycline in the feed of swine, and the relationships of currently approved products as innovative or follow-on.

11. Alpharma denies the allegations of Paragraph 11 of the Complaint except that Alpharma admits that Alpharma employee Dr. Teddi Wolff presented the results of a study concerning Alpharma's Aureomycin[®] 90G and 220G at the American Association of Swine Veterinarians on Sunday, March 6, 2006 in Kansas City, Missouri.

12. Alpharma denies the allegations of the preamble of Paragraph 12 bridging pages 3-4 of the Complaint except that Plaintiff admits to have issued the publication attached as Exhibit A to the Complaint and to have issued the publication attached as Exhibit B to the Complaint (but denies having knowledge or information sufficient to form a belief as to whether the publications attached as Exhibits A and B to the Complaint were produced, advertised and provided to plaintiff's customers and potential customers).

13. Alpharma denies the allegations of Paragraph 12(a) of the Complaint and refers the Court to Exhibits A and B to the Complaint.

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14. Alharma denies the allegations of Paragraph 12(b) of the Complaint except that Alharma admits that the studies described in Exhibits A and B to the complaint yielded the data and information described in those exhibits; Alharma refers the Court to Exhibits A and B to the Complaint.

15. Alharma denies the allegations of Paragraph 12(c) of the Complaint except that Alharma admits that the United States Pharmacopeia chapter cited as reference No. 5 in Exhibit B to the Complaint relates to dissolution studies, and Alharma refers the Court to Exhibit B to the Complaint.

16. Alharma denies the allegations of Paragraph 12(d) of the Complaint except that Alharma admits that (i) the studies described in Exhibits A and B to the complaint yielded the data and information described in those exhibits; and (ii) that tetracyclines dissolved in the swine stomach may be absorbed in swine small intestine under some conditions; Alharma refers the Court to Exhibits A and B to the Complaint.

17. Alharma denies the allegations of Paragraph 12(e) of the Complaint except that Alharma admits that Alharma provided financial support for scientific research described in the publication attached as Exhibit C to the Complaint.

18. Alharma denies the allegations of Paragraph 12(f), including subsections 1 through 9, of the Complaint and refers the Court to Exhibits A through C to the Complaint.

19. Alharma denies the allegations of Paragraph 12(g) of the Complaint except that Alharma admits to have issued the publication attached as Exhibit C to the Complaint (but denies having knowledge or information sufficient to form a belief as to whether that publication was distributed or caused to be distributed to “plaintiff’s customers, potential customers”); Alharma refers the Court to Exhibits C and D to the Complaint.

ALPHARMA’S ANSWER AND COUNTERCLAIMS

20. Alpharma denies the allegations of Paragraph 12(h) of the Complaint, except that Alpharma (i) denies having knowledge or information sufficient to form a belief as to the contents of Exhibits E and F because the copies served are illegible; and (ii) admits that Aureomycin[®] 90G must be sold and promoted in compliance with the Federal Food, Drug, and Cosmetic Act to the extent applicable; however, Alpharma denies the allegation that 21 U.S.C. § 352(n) (concerning prescription drugs) applies to the over-the-counter drug product Aureomycin[®] 90G. Alpharma refers the Court to Exhibits A through E to the Complaint.

21. Alpharma denies the allegations of Paragraph 13 of the Complaint.

COMPLAINT COUNT I

(Lanham Act Claim)

22. In response to the allegations of Paragraph 14 of the Complaint, Alpharma repeats and incorporates its responses to Paragraphs 1 through 13 of the Complaint as if fully set forth herein.

23. Alpharma denies the allegations of Paragraph 15 of the Complaint.

24. Alpharma denies the allegations of Paragraph 16 of the Complaint.

25. Alpharma denies the allegations of Paragraph 17 of the Complaint.

26. Alpharma denies the allegations of Paragraph 18 of the Complaint.

COMPLAINT COUNT II

(Nebraska Consumer Protection Act)

27. In response to the allegations of Paragraph 19 of the Complaint, Alpharma repeats and incorporates its responses to Paragraphs 1 through 18 of the Complaint as if fully set forth herein.

28. Alpharma denies the allegations of Paragraph 20 of the Complaint.

ALPHARMA'S ANSWER AND COUNTERCLAIMS

DEFENDANTS' AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

29. Defendant and Counterclaim-Plaintiff Alharma asserts the following defenses and counterclaims:

FIRST AFFIRMATIVE DEFENSE

30. For its First Affirmative Defense, Alharma states that the Complaint fails to state a claim upon which the relief sought can be granted.

SECOND AFFIRMATIVE DEFENSE

31. For its Second Affirmative Defense, Alharma states that all statements in Exhibits A through D to the Complaint are truthful, accurately reflect the nature, characteristics, and qualities of the products tested, including Alharma's products and commercial activities, and that all of Alharma's assertions supported by testing are substantiated by reliable testing.

THIRD AFFIRMATIVE DEFENSE

32. For its Third Affirmative Defense, Alharma states that Exhibits C and D to the Complaint are not commercial advertisements or promotions but scientific publications for an academic audience. Plaintiff's Complaint therefore fails to state a claim upon which relief can be granted with regard to Exhibits C and D to the Complaint.

FOURTH AFFIRMATIVE DEFENSE

33. For its Fourth Affirmative Defense, Alharma states that it is not liable to Plaintiff because the people of the State of Nebraska were not affected and therefore the public interest not impacted by Alharma's publications attached as Exhibits A through D to the Complaint.

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FIFTH AFFIRMATIVE DEFENSE

34. For its Fifth Affirmative Defense, Alharma states that it is not liable to Plaintiff because of the affirmative defense of laches. The publications attached as Exhibits A through D to the Complaint were issued in approximately 2006 and Pennfield failed to raise its allegations against Alharma until September 30, 2009.

SIXTH AFFIRMATIVE DEFENSE

35. For its Sixth Affirmative Defense, Alharma states that it is not liable to Plaintiff because of the affirmative defense of acquiescence. Pennfield has acquiesced in Alharma's publications since approximately 2006.

SEVENTH AFFIRMATIVE DEFENSE

36. For its Seventh Affirmative Defense, Alharma states that it is not liable to Plaintiff because of the affirmative defense of waiver.

EIGHTH AFFIRMATIVE DEFENSE

37. For its Eighth Affirmative Defense, Alharma states that it is not liable to Plaintiff because of the affirmative defense of promissory and equitable estoppel.

NINTH AFFIRMATIVE DEFENSE

38. For its Ninth Affirmative Defense, Alharma states that it is not liable to Plaintiff because of the affirmative defense of unclean hands.

TENTH AFFIRMATIVE DEFENSE

39. For its Tenth Affirmative Defense, Alharma states that it is not liable to Plaintiff because of the affirmative defense of failure of conditions precedent. Plaintiff provided Alharma with no notice of its allegations and gave Alharma no opportunity to modify or correct its publications.

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ELEVENTH AFFIRMATIVE DEFENSE

40. For its Eleventh Affirmative Defense, Alpharma states that it is not liable to Plaintiff because Plaintiff failed to mitigate its alleged damages.

TWELVETH AFFIRMATIVE DEFENSE

41. The purported declaratory relief sought by Plaintiff is barred as duplicative and/or unnecessary.

THIRTEENTH AFFIRMATIVE DEFENSE

42. The injunctive relief sought by Plaintiff is moot in whole or in part.

FOURTEENTH AFFIRMATIVE DEFENSE

43. For its Fourteenth Affirmative Defense, Alpharma states that it defers to the FDA, FTC, or other specialized regulatory agency, the determination of certain issues raised in this action before the Court that fall within the primary jurisdiction of the FDA, FTC, or such other regulatory agency.

COUNTERCLAIMS

44. Counterclaim-Plaintiff Alpharma hereby repeats and re-alleges its allegations in Paragraphs 1 through 43 above.

ALLEGATIONS OF FACT COMMON TO ALPHARMA'S COUNTERCLAIMS AND AFFIRMATIVE DEFENSES

45. Alpharma and its corporate predecessors have pioneered the use of tetracycline antibiotics as a class, which includes chlortetracyclines, oxytetracyclines, and tetracyclines, and established Aureomycin[®] chlortetracyclines as an innovative product line time and time again over a period of more than 50 years, beginning in 1949 when the first Aureomycin[®] chlortetracycline was developed as an additive to livestock feed. Aureomycin[®] chlortetracyclines were the first true broad-spectrum antibiotics and made it possible for ranchers

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to treat large numbers of animals at the same time for the respiratory infections that previously ravaged their herds.

46. Consistent with its pioneer status, Alpharma presently holds thirty-three (33) NADA for products comprising a tetracycline alone or in combination with other drugs including twenty-nine (29) approved NADAs for chlortetracycline (“CTC”) products, two (2) approved NADAs for oxytetracycline products (“OTC”), and two (2) approved NADAs for tetracycline (“TC”) products. Upon information and belief, Pennfield has entered the field no earlier than 1996 and has a total of only four (4) approved NADAs for products comprising a tetracycline, including three (3) approved NADAs for CTC products and one (1) approved NADA for an OTC product, and eight (8) approved Abbreviated New Animal Drug Applications (“ANADAs”) for CTC products. Also upon information and belief, Pennfield has no approved NADAs or ANADAs for a product that includes tetracycline per se.

47. Pennfield made false and misleading statements of fact about its products by referring to Pennfield as “# 1 in Tetracyclines” and “The Technology Leader in Tetracyclines” in, at a minimum, the Feedstuffs 2010 calendar. A copy of Pennfield’s advertisement is attached as Exhibit 1. Both statements of fact, when read separately and when read in conjunction, are false and misleading because Pennfield is not “# 1 in Tetracyclines” and not “The Technology Leader in Tetracyclines.” These factual statements falsely and misleadingly suggest that Pennfield’s products are superior in technology to competitors’ products (including Alpharma’s) when they are not. More specifically, the statements are false because (i) Pennfield has no approved NADAs or ANADAs for a product that includes tetracycline per se; (ii) Pennfield was not the first in time to receive regulatory approval for and/or enter the market with their chlortetracycline or oxytetracycline products; (iii) Pennfield’s

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chlortetracycline and oxytetracycline products are not technologically superior to Pennfield competitors' products, including Alharma's chlortetracycline, oxytetracycline, and tetracycline products; and (iv) Pennfield's chlortetracycline and oxytetracycline products are not "# 1" in any other respects such as, for example, sales, volume of product sold, product performance, or customer service when compared to competitors.

48. Upon information and belief, Pennfield's false, misleading, and demeaning advertisement began in 2009 and has damaged and continues to damage Alharma including harm to Alharma's reputation, goodwill, and sales of its chlortetracycline, oxytetracycline, and tetracycline products, which include at least Alharma's Aureomycin[®], Tet-Sol[®], and Solu-Tet[®] product lines.

PARTIES FOR COUNTERCLAIMS

49. Alharma is a corporation organized under the laws of the state of Delaware with its principal place of business at 400 Crossing Blvd., Bridgewater, New Jersey 08807. Alharma is a global specialty pharmaceutical company and a major producer of pharmaceutical products for humans and animals. Alharma is among the world's leading producers of several specialty pharmaceutical-grade bulk antibiotics and is internationally recognized as a leading provider of pharmaceutical products for animal health. Alharma's animal health business is based on a portfolio of anti-infective animal health products that are added to the feed and water of livestock and poultry and includes products with the compounds chlortetracycline, oxytetracycline, and tetracycline.

50. Pennfield is a Nebraska corporation with its principle place of business in Omaha, Douglas County, Nebraska. Pennfield is engaged in the development, manufacturing, distribution and sale of pharmaceutical products, including animal biological and pharmaceutical

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products. Pennfield's portfolio of products includes products containing the compounds chlortetracycline and oxytetracycline.

JURISDICTION AND VENUE FOR COUNTERCLAIMS

51. This Court has original jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 & 1338 and 15 U.S.C. § 1121, and supplemental jurisdiction over the state law claim under 28 U.S.C. § 1367. This Court also has jurisdiction, including supplemental jurisdiction, over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338 & 1367 and 15 U.S.C. § 1121.

52. This Court has personal jurisdiction over Counter-Defendant because Pennfield is incorporated in the State of Nebraska, has its principle place of business in Omaha, Nebraska, and regularly conducts business in the State of Nebraska.

53. Venue is proper in the Federal District of Nebraska pursuant to 28 U.S.C. § 1391.

FIRST COUNTERCLAIM AND FIFTEENTH AFFIRMATIVE DEFENSE

(15 U.S.C. § 1125(a))

54. Counterclaim-Plaintiff Alpharma hereby repeats and re-alleges its allegations above.

55. Pennfield made false and misleading statements of fact about its products by referring to Pennfield as “# 1 in Tetracyclines” and “The Technology Leader in Tetracyclines” in, at a minimum, the Feedstuffs 2010 calendar. A copy of Pennfield's advertisement in the Feedstuffs 2010 calendar is attached as Exhibit 1. Both statements of fact, when read separately and when read in conjunction, are false and misleading because Pennfield is not “# 1 in Tetracyclines” and not “The Technology Leader in Tetracyclines.” These factual statements incorrectly suggest that Pennfield's products are superior in technology to

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competitors' products (including Alparma's) when they are not. More specifically, the statements are false because (i) Pennfield has no approved NADAs or ANADAs for a product that includes tetracycline per se; (ii) Pennfield was not the first in time to receive regulatory approval for and/or enter the market with their chlortetracycline and oxytetracycline products; (iii) Pennfield's chlortetracycline and oxytetracycline products are not technologically superior to Pennfield competitors' products, including Alparma's chlortetracycline, oxytetracycline, and tetracycline products; and (iv) Pennfield's chlortetracycline and oxytetracycline products are not "# 1" in any other respects such as, for example, sales, volume of product sold, product performance, or customer service when compared to competitors.

56. Finally, even if the Court should find that Pennfield's advertisement is literally true, the advertisement renders a false impression when viewed in context and has the tendency to and has mislead or deceived customers and potential customers.

57. Pennfield's statements in the advertisement have deceived or had the tendency to deceive a substantial segment of its audience into believing in the truth of the statements asserted by Pennfield.

58. The deception created by Pennfield is material in light of the broad circulation of the false advertisement as well as the far-reaching nature of the statement, essentially claiming superiority of Pennfield's chlortetracycline and oxytetracycline products over all competitors.

59. Pennfield caused the false statement to enter interstate commerce by distributing or causing the distribution of the advertisement in the 2010 Feedstuffs calendar in the States of Nebraska and New Jersey, and throughout the United States.

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60. Pennfield's aforementioned advertisement has caused and is likely to cause in the future damages to Alpharma in an amount to be determined at trial.

61. Pennfield's false advertisement will continue, and will continue to cause substantial and irreparable injury to Alpharma, unless enjoined by this court.

62. Alpharma has no adequate remedy at law.

SECOND COUNTERCLAIM AND SIXTEENTH AFFIRMATIVE DEFENSE

(Neb. Rev. Stat. § 59-1601 seq.)

63. Counterclaim-Plaintiff Alpharma hereby repeats and re-alleges its allegations above.

64. Alpharma is injured in its business and the Nebraska public interest adversely impacted by Pennfield's false and misleading advertisement set forth in Exhibit 1 hereto which constitutes an unfair method of competition and unfair and deceptive act and practice in Pennfield's conduct of trade and commerce. Pennfield's false advertisement will likely confuse the public by deceiving customers and potential customers about the technological superiority of Pennfield's products over Alpharma's and other competitors' products. The public interest is served by preventing such consumer confusion in the market place and Pennfield has therefore violated Neb. Rev. Stat. §§ 59-1601, 1602 and 1609.

THIRD COUNTERCLAIM AND SEVENTEENTH AFFIRMATIVE DEFENSE

(Declaratory Judgment)

65. Counterclaim-Plaintiff Alpharma hereby repeats and re-alleges its allegations above.

66. There exists an actual and justiciable controversy between Alpharma and Pennfield, capable and ripe for determination by declaratory judgment by this Court as to

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whether (i) Alpharma's publications attached as Exhibits A through D to the Complaint were truthful and/or did not constitute advertisements or promotions that impacted the public interest in the State of Nebraska and (ii) Pennfield has the right to continue to use and distribute the advertising, a copy of which is attached as Exhibit 1 to this Pleading.

67. Alpharma seeks a declaration from this Court under the Federal Declaratory Judgment Act, 29 U.S.C. §§ 2201–2202, decreeing that (i) Alpharma's statements in the publications attached as Exhibits A through D to the Complaint are truthful; (ii) Pennfield's advertisement attached as Exhibit 1 to this Answer and Counterclaims is false and misleading; and (iii) Alpharma is entitled to recover costs, including attorneys' fees, and disbursement incurred in connection with this action.

68. A declaratory judgment setting forth the respective rights of the parties on this issue is necessary to resolve this controversy.

ATTORNEYS' FEES

69. Alpharma requests an award of attorneys' fees in defending the claims brought against it and in prosecuting its counterclaims under 15 U.S.C. § 1117(a); 29 U.S.C. §§ 2201–2202; and Neb. Rev. Stat. §59-1609.

WHEREFORE, Defendant and Counterclaim-Plaintiff Alpharma respectfully prays for a judgment in its favor and against Plaintiff and Counterclaim-Defendants Pennfield:

- a. dismissing the Complaint and all claims and relief sought therein in their entirety and with prejudice;
- b. awarding damages in an amount to be proved at trial, including pre-judgment and post-judgment interest;

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- c. entering an order with respect to the Third Counterclaim, declaring and finding that:
 - i. Alharma's statements in the publications attached as Exhibits A through D to the Complaint are truthful; and
 - ii. Pennfield's advertisement attached as Exhibit 1 to this Answer and Counterclaims is false and misleading.
- d. awarding Alharma's attorneys' fees and costs and disbursements incurred in connection with this action;
- e. finding that Pennfield, its officers, agents, affiliates, subsidiaries, employees, attorneys and representatives and all those in privity or acting in concert with Pennfield, and each and all of them, be permanently enjoined and restrained from directly or indirectly distributing the advertisement attached as Exhibit 1 to this Answer and Counterclaims.
- f. directing Pennfield to immediately cancel any further printing and distribution the advertisement attached as Exhibit 1 to this Answer and Counterclaims and recall from all distributors, retailers, or other recipients any and all existing copies of the same; and
- g. granting Alharma such other further relief as the Court deems just and proper.

Dated: November 25, 2009

KING & SPALDING LLP

Respectfully submitted,

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Attorney for Defendant Alparma Inc.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on November 25, 2009, I electronically filed a true and correct copy of Defendant's Answer and Counterclaims with the Clerk of Court using the CM/ECF system, which will send notification of such filing to the following: Brien N. Welch, Cassem, Tierney, Adams, Gotch & Douglas, counsel for Plaintiff, 8805 Indian Hills Drive, Suite 300, Omaha, Nebraska 68114,

and I hereby certify that I have mailed by United States Postal Service the document to the following CM/ECF participants: Brien N. Welch, Cassem, Tierney, Adams, Gotch & Douglas, counsel for Plaintiff, 8805 Indian Hills Drive, Suite 300, Omaha, Nebraska 68114.

s/Franz Michael Stenglein